**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| BARBARA MACK, as ADMINISTRATRIX of the ESTATE of WILLIAM A. MACK, JR., deceased, | |
| Plaintiff, | Civil Action No. 10-2142 |
| v. | |
| VENTRACOR, INC., et al. | |
| Defendants. | |

**ORDER**

AND NOW, this _____ of _____, 2010, upon consideration of plaintiff's Motion to Remand, and for costs, expenses, and attorneys' fees, and defendants Rohinton J. Morris, M.D., Michael A. Acker, M.D., Mariell L. Jessup, M.D. and the Trustees of the University of Pennsylvania's Response in opposition thereto, it is hereby ORDERED that said Motion is DENIED.

BY THE COURT

_____
J.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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|---|---|
| BARBARA MACK, as ADMINISTRATRIX of the ESTATE of WILLIAM A. MACK, JR., deceased, | |
| Plaintiff, | Civil Action No. 10-2142 |
| v. | |
| VENTRACOR, INC., et al. | |
| Defendants. | |

**CERTAIN DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION TO REMAND AND FOR COSTS, EXPENSES AND ATTORNEYS' FEES**

Defendants, Rohinton J. Morris, M.D., Michael A. Acker, M.D., Marriell L. Jessup, M.D. and the Trustees of the University of Pennsylvania, t/d/b/a University of Pennsylvania, The Hospital of the University of Pennsylvania and the University of Pennsylvania Health System, by and through their counsel, Christie, Pabarue, Mortensen and Young, a Professional Corporation, hereby respond in opposition to Plaintiff's Motion to Remand this action to the Philadelphia County Court of Common Pleas, and aver as follows:

For the reasons set forth in the accompanying Memorandum of Law, responding defendants respectfully request that this Court deny plaintiff's motion to remand this action to the Philadelphia Court of Common Pleas.

Respectfully submitted,

BY: _____

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Mariell L. Jessup, M.D. and
the Trustees of the University of
Pennsylvania

Dated: 7/7/10

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| BARBARA MACK, as ADMINISTRATRIX of the ESTATE of WILLIAM A. MACK, JR., deceased,<br><br>Plaintiff,<br><br>v.<br><br>VENTRACOR, INC., et al.<br><br>Defendants. | Civil Action No. 10-2142 |

**CERTAIN DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO REMAND AND FOR COSTS, EXPENSES AND ATTORNEYS' FEES**

Defendants, Rohinton J. Morris, M.D., Michael A. Acker, M.D., Mariell L. Jessup, M.D. and the Trustees of the University of Pennsylvania, t/d/b/a University of Pennsylvania, The Hospital of the University of Pennsylvania and the University of Pennsylvania Health System, by and through their counsel, Christie, Pabarue, Mortensen and Young, a Professional Corporation, respectfully submit this Memorandum of Law in opposition to Plaintiffs' Motion to Remand and for an award of costs, expenses and attorneys' fees.

## I. INTRODUCTION

Responding defendants removed this matter from the Philadelphia Court of Common Pleas to this Court on the basis that plaintiff's Complaint raised issues involving substantial questions of federal law thereby giving rise to federal court jurisdiction. A copy of plaintiff's Complaint is attached hereto as Exhibit "A". Specifically, plaintiff contends in her Complaint that responding defendants are liable for failing to properly obtain Mr. Mack's informed consent

(Count VIII) and for fraudulent misrepresentation[1] (Count IX) by allegedly misleading and misrepresenting to Mr. Mack his legal rights based solely on the language in Research Subject Informed Consent Form that Mr. Mack signed in connection with his participation in the clinical trial at issue. In particular, plaintiff takes issue with the language in the consent form which provides that nothing in the informed consent "shall act to waive any of your legal rights or to release the University of Pennsylvania Health System and School of Medicine, the study sponsor, Ventracor, Inc., or any of their agents from liability for negligence." See consent form attached as Exhibit "B" to plaintiff's Complaint at p. 11. These claims raise issues involving substantial questions of federal law based on specific federal regulations governing informed consent in clinical trials.

In Grable & Sons Metal Products, Inc. v. Darue Engr'g & Mf'g , 545 U.S. 308 (2005), the Supreme Court issued a landmark opinion which substantially clarified the legal grounds for invoking federal question jurisdiction over state law claims. The Court reaffirmed

> the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.

Id., at 312. Further, the Grable Court specifically rejected the argument advanced by plaintiff in her Motion to Remand that a federal private right of action was a prerequisite for exercising federal question jurisdiction. Id. at 318. The instant case clearly meets the requirements for federal question jurisdiction pursuant to the Grable decision, as the entirety of plaintiff's claim for battery/lack of informed consent and for fraudulent misrepresentation are based exclusively upon an interpretation of regulations promulgated by the United States Food and Drug

[1] Plaintiff also appears to base her Breach of Fiduciary Duty Claim, Count X, on the same facts.

Administration ("FDA") governing informed consent in clinical trials. See 21 C.F.R. §§ 50.20, 50.25, 50.27.

The United States has long taken a great interest in matters relating to research on human subjects. The FDA promulgated its first regulations requiring informed consent of human subjects following a Congressional mandate in 1962 that consent be obtained from patients/subjects in drug research. Abdullahi v. Pfizer, Inc., 562 F.3d 163, 182 (2nd Cir. 2009). One of the principal sources on which the federal government relied in outlawing non-consensual human medical experimentation was the Nuremberg Code, which emphasized the requirement that a human subject must voluntarily consent to undergo medical experimentation. Id. The Nuremberg Code was formulated and utilized in the prosecution of Nazi Germany physicians for war crimes and crimes against humanity for conducting medical experiments without the patients' consent. Id. at 178.

Various federal agencies have adopted regulations to address human research studies in the form of clinical trials. The "Common Rule" is the term used by federal agencies which have adopted regulations governing human subjects of research. These regulations incorporate the guidelines of the Belmont Report, which was published in 1978 by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The Belmont Report identified basic ethical principles governing biomedical and behavioral research on human subjects and emphasized the importance of informed consent. Abdullahi, supra at 182. The regulations implemented by the FDA in accordance with the Common Rule and the regulatory authority provided under the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, et seq. (and the Medical Device Amendments of 1976) pertain to research studies (clinical trials) that are designed to develop new drugs, medical devices and biological products, such as the medical

device at issue in this case (a so-called left ventricular assist device, intended to help a weak heart pump sufficient blood). 21 C.F.R. § 50.1, et seq.

The FDA has issued detailed regulations addressing the subject of informed consent in clinical trials relating to these products. 21 C.F.R. §§ 50.20, 50.25, 50.27. Pursuant to the Common Rule, these regulations largely mirror regulations promulgated by the United States Department of Health and Human Services ("HHS") that apply to federally funded research. See 45 C.F.R. §§ 46.116, 46.117. Among other requirements, the FDA regulations expressly state that:

> **No informed consent**, whether oral or written, **may include any exculpatory language through which the subject** or the representative **is made to waive** or appear to waive **any of the subject's legal rights, or releases the investigator, the sponsor, the institution, or its agents from liability for negligence**.

21 C.F.R. § 50.20 (emphasis added). See also 45 C.F.R. § 46.116 (equivalent HHS regulation). The FDA regulations also specify information that must be provided to the research subject and with regard to the documentation of informed consent by the use of a written consent form embodying the elements identified by the FDA. 21 C.F.R. §§ 50.25, 50.27.[2]

Here, the written consent form ("University of Pennsylvania Research Subject Informed Consent Form") utilized by moving defendants for the clinical trial in which Mr. Mack enrolled, addressed the FDA regulatory requirement quoted above by explicitly informing Mr. Mack that:

> Nothing in this informed consent shall act to waive any of your legal rights or to release the University of Pennsylvania Health System and School of Medicine, the study sponsor, Ventracor, Inc., or any of their agents from liability for negligence.

See Exhibit "B" to plaintiff's Complaint at p. 11.

[2] See FDA list of requirement elements for informed consent set forth on p. 13, infra.

It is noteworthy that plaintiff dismissed an earlier action removed to federal court[3] involving essentially identical claims and issues, but in which the Complaint filed by plaintiff specifically cited federal regulations relating to informed consent in clinical research trials as the legal basis for her claim for battery/informed consent. See plaintiff's Eighth Amended Complaint filed in Barbara Mack v. Ventracor, Inc., et al., CCP Phila. Cty., February Term, 2009, No. 633, attached hereto as Exhibit "B". Specifically, plaintiff alleged as follows in the Eighth Amended Complaint filed in the underlying matter:

> 52. The IRB[4] knew and understood the mandates of the Code of Federal Regulations, 45 CFR 46, and the strictures of informed consent and the informed consent process. Both Ventracor and the University of Pennsylvania represented to William Mack that he had legal rights arising out of the use of the VentrAssist by way of the informed consent form, and have waived any affirmative defenses based upon preemption doctrine and subject matter jurisdiction in that regard.
>
> 134. 45 C.F.R. § 46.116 (General requirements for informed consent) provides in relevant part that:
>
> > The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
>
> 139. The University of Pennsylvania violated 45 C.F.R. § 46, and the "Common Rule", which applies to all federally regulated and/or funded research performed at the University of Pennsylvania.
>
> 140. At all times relevant hereto, the University of Pennsylvania had a "Federal Wide Assurance" ["FWA"] in place, which was submitted to the Office of Human Research Subject Protection of the U.S. Department of Health and Human Services. The FWA acts as a contract between the institution and

[3] Plaintiff dismissed this action shortly after it was removed and subsequently refiled in the state court again by way of the Complaint that started the action that was removed to and is presently before the Court. (Exhibit "A" hereto.)

[4] The IRB is the Internal Review Board, which is the hospital organization that reviews and approves (or disapproves) aspects of proposed and operating clinical trials.

> the government and assures that research at the University of Pennsylvania will be conducted in compliance with federal regulations and accepted ethical principles.
>
> 141. The research conducted on William Mack was not conducted in compliance with federal regulations and accepted ethical principles.

See Exhibit "B" (emphasis in original).

In an obvious attempt to avoid federal court jurisdiction, plaintiff dismissed the action in which the aforementioned allegations were pled and filed a new Complaint in state court (the action removed to this Court by moving defendants) absent the above allegations or any reference to federal regulations governing informed consent. Instead, plaintiff cites the Pennsylvania Medical Care Availability and Reduction of Error ["MCARE"] Act, 40 P.S. § 1303.504, as the legal basis for her claim that responding defendants are liable for lack of informed consent/battery and for fraudulent misrepresentation for allegedly misrepresenting Mr. Mack's legal rights in the consent form. However, the state informed consent statute clearly has no bearing whatsoever on plaintiff's theory of liability in this case.

While the MCARE Act is applicable to procedures involving experimental devices, there is nothing in the Act which provides that a health care provider must provide a patient with a description of his legal rights. Rather, the Act states, in pertinent part:

> (b) **Description of procedure.** – Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure.

40 P.S. § 1303.504 (emphasis supplied). Indeed, the MCARE Act is silent as to the required content of an informed consent form or as relates to the issues of waiver of legal rights in the context of informed consent, in stark contrast to the FDA and HHS regulations. Nowhere in her Complaint does plaintiff contend that Mr. Mack was not informed by responding defendants of

his medical procedure or the risks or alternatives of that procedure (which information is the totality of what the Pennsylvania MCARE Act required for consent to be informed.[5] Although plaintiff avers in the Complaint that Mr. Mack was not advised of true and accurate information concerning the risks and alternatives of the procedure, such claims are premised entirely upon responding defendants' purported failure to properly inform him of his legal rights, as opposed to claims that he was not properly informed of the medical risks of the procedure or possible medical alternatives. See Exhibit "A", Count VIII to Complaint, ¶¶ 180-184.

While plaintiff's Eight Amended Complaint (Exhibit "B") may have made the federal question at the heart of plaintiff's informed consent/battery claim[6] more easily identifiable, the Complaint now before the Court continues to demonstrate that the sole factual and legal basis for the plaintiff's claims is not any violation of the Pennsylvania informed consent statute, 40 P.S. § 1303.504, but rather an alleged violation of FDA regulations 21 C.F.R. §§ 50.20, 50.25 and 50.27, allegedly by misrepresenting and otherwise making a "charade" of Mr. Mack's legal rights. See, Exhibit "A" at ¶¶ 26, 70, 190.

Despite plaintiff's attempt to redefine her claim as being governed by interpretation of state law, the issues raised herein relating to informed consent rise or fall purely under interpretation of applicable federal regulations. Plaintiff is raising a direct challenge to the requirements and meaning of FDA regulations relating to informed consent for clinical trials involving medical devices such as the Ventracor VentrAssist LVA4 device surgically implanted in Mr. Mack. The United States has a substantial interest in the need for uniformity of

[5] The consent form provides detailed information regarding risks to and alternatives of the procedure. See consent form, Exhibit "B" to plaintiff's Complaint at pp. 5-7.

[6] The Eighth Amended Complaint did not name any physician defendants and did not assert the fraudulent misrepresentation nor breach of fiduciary claims contained in the Complaint (Counts IX and X) now before this Court.

interpretation of its regulations governing informed consent in clinical trials. Resolution of plaintiff's claims necessarily turns on whether responding defendants complied with the federal regulatory requirements for informed consent applicable to clinical trials like the one in which Mr. Mack enrolled. Accordingly, the Court has jurisdiction over the subject matter of this case and plaintiff's Motion to Remand should be denied.

## II. FACTUAL AND PROCEDURAL BACKGROUND

This matter involves claims relating to the death of plaintiff's decedent, William A. Mack, Jr., due to an alleged design defect in a medical device provided by co-defendant Ventracor, Inc. Mr. Mack, then suffering from end-stage cardiac disease, was offered the opportunity and agreed to participate in a federally-approved clinical research study involving the VentrAssist LVA4 device provided by co-defendant Ventracor in an effort to save and prolong his life. See Exhibit "A" at ¶¶ 55-63.

Pursuant to an Investigational Device Exemption ("IDE") approved by the FDA, Ventracor worked with the FDA to design clinical trial protocols for the VentrAssist LVA4 device which were utilized at more than twenty research centers, including the Hospital of the University of Pennsylvania ("HUP"). An IDE allows the investigational device to be used in a clinical trial in order to collect safety and effectiveness data required to support a Premarket Approval application or a Premarket Notification submission to the FDA. See 21 C.F.R. § 812.

As plaintiff previously asserted in her previously filed Complaint, prior to the submission of the IDE application to the FDA, meetings were held involving individuals associated with Ventracor, the FDA and HUP "to formulate with the FDA a proposal for a controlled clinical trial for the purpose of determining the safety and efficacy of the VentrAssist utilizing human research subjects, and to obtain feedback, revisions and guidance from the FDA on the research

proposal." See Exhibit "B", ¶ 45. Plaintiff further averred that the HUP Institutional Review Board "knew and understood the mandates of the Code of Federal Regulations regarding the use and protection of human subjects in clinical research, 45 C.F.R. 46 and the strictures of informed consent and the informed consent process." Id, ¶ 52.

Plaintiff initially filed suit more than one year ago in the Philadelphia Court of Common Pleas against HUP and co-defendant, Ventracor, Inc. based on the same subject matter as involved in the action herein. On February 19, 2010, more than one year after plaintiff filed her original Complaint in the underlying action, plaintiff filed the Eighth Amended Complaint attached as Exhibit "B" and, for the first time, asserted a cause of action for battery against HUP. Plaintiff asserted in that version of the Complaint that HUP was liable for battery based on a failure to adhere to the informed consent provisions set forth in federal regulations, specifically 45 C.F.R. § 46.116[7] and the Common Rule. Plaintiff relied upon these regulations to support her claim that the Hospital made material misrepresentations regarding the patient's legal rights as described in the informed consent form presented to Mr. Mack prior to his surgery. See Exhibit "B," ¶¶ 132 – 142.

On the basis of 28 U.S.C. §1331, federal question jurisdiction, defendants removed the underlying action to the Eastern District of Pennsylvania. Barbara Mack v. Ventracor, Inc., et al., 5:10-CV-01121. The underlying action was then voluntarily dismissed by plaintiff on March 26, 2010. The action at bar was filed via Complaint on March 31, 2010, only five days later.

In Count VIII of the Complaint before the Court, plaintiff pleads a claim for battery/informed consent against responding defendants as she did in the underlying action. In Count IX, plaintiff also asserts a new claim for fraudulent misrepresentation based upon the

[7] As noted above, 45 C.F.R. § 46.116 was promulgated by the Department of Health and Human Services. The identical provisions relating to informed consent which are applicable to FDA-approved clinical trials are set forth at 21 C.F.R. §§ 50.20 and 50.25.

language of the consent form. As was asserted in the underlying action, plaintiff takes particular issue with the following language set forth in the informed consent form signed by Mr. Mack:

> Nothing in this informed consent **shall act to waive any of your legal rights or to release** the University of Pennsylvania Health System and School of Medicine, the study sponsor, Ventracor, Inc., or any of their agents **from liability for negligence**.

See consent form, Exhibit "B" to Plaintiff's Complaint at p. 11 (emphasis added). Plaintiff avers that the inclusion of such language in the consent form amounted to a "charade and illusion" that Mr. Mack retained a full panoply of legal rights and obligations, as allegedly was demonstrated by the legal defenses asserted by responding defendants in the underlying action. See Exhibit "A' at ¶¶ 26, 70, 190.

Responding defendants timely removed the matter to this Court on May 10, 2010. Plaintiff subsequently moved for remand of the action to the Philadelphia County Court of Common Pleas.

## III. LEGAL ARGUMENT

### A. Legal Standard for Removal

The pertinent statute regarding removal of actions from state court to federal court is 28 U.S.C. § 1441(a) which provides that:

> Except as otherwise expressly provided by Act of Congress, any civil action brought in a state court of which the district courts of the United States have original jurisdiction, may be removed by the defendant, or the defendants, to the district court of the United States for the District and Division embracing the place where such action is pending.

The statute which allows the district court to exercise jurisdiction involving a federal question is 28 U.S.C. §1331, which provides that "the district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." A case "arises under" federal law within the meaning of §1331 "if a well-pleaded complaint establishes either

that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law," Empire Health Choice Assurance, Inc. v. McVeigh, 547 U.S. 677, 690 (2006) (quoting Franchise Tax Bd. of Calif. v. Construction Laborers Vacation Trust for Southern Cal., 463 U.S. 1 (1983).

Federal regulations are considered to have the same binding legal effect as statutory law, as long as the regulations are a reasonable interpretation of the underlying statute. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S 837, 843-44 (1984). As the Supreme Court has noted, "the power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress. Morton v. Ruiz, 415 U.S. 199, 231 (1974).

In Grable & Sons Metal Products, Inc. v. Darue Engr'g & Mf'g , 545 U.S. 308 (2005) the Supreme Court discussed the application of federal question jurisdiction and announced the following test:

> [T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.

Id., 545 U.S. at 314. See, also, Koresko v. Murphy, 464 F. Supp. 2d 463 (E.D. Pa. 2006) (plaintiff's motion for remand denied since plaintiff's claim of rescission of contract necessarily raised a federal issue); McClure Telephone Co. v. AT&T Communications of Ohio, Inc., et al. 650 F. Supp. 2d 699 (N.D. Ohio 2009) (plaintiff's motion for remand denied since substantial federal question raised as to whether the first leg of an international call that occurs intrastate constitutes an international call for jurisdictional purposes); Wirth v. Aetna U.S. Healthcare, 2004 U.S. Dist. Lexis 1787 (E.D. Pa. 2004) (plaintiff's motion for remand denied since claims

are completely preempted by ERISA and the federal court has subject matter jurisdiction over them.); Nicodemus v. Union Pacific Corp., 440 F.3d 1227 (10th Cir. 2006) (federal forum is appropriate in case where contested interpretation of federal land-grant statutes between landowners and railroad company involved a substantial federal issue.)

**B. Plaintiff's Complaint Raises Substantial and Disputed Federal Issues Regarding Informed Consent Making Federal Court the Appropriate Forum for This Matter**

**1. Federal question jurisdiction is appropriate based on the federal government's substantial interest in ensuring that informed consent is properly obtained from research subjects in clinical trials**

The FDA regulation found at 21 C.F.R § 50.20 provides general requirements for informed consent of human subjects: "… no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained a legally effective informed consent of the subject or the subject's legally authorized representative." This section further provides that "… no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." 21 C.F.R. § 50.20. See also 45 C.F.R § 46.116. This section is at the heart of plaintiff's battery and fraudulent misrepresentation claims against HUP and Drs. Morris, Acker and Jessup. Plaintiff is alleging that defendants misrepresented to Mr. Mack his legal rights by advising him that execution of the consent form did not waive his legal rights to pursue a claim for negligence. Plaintiff claims that defendants' subsequent actions in pleading various defenses to her numerous forms of Complaint is evidence that the consent form amounted to a "charade" and an "illusion" (See Exhibit "A" at ¶¶ 26, 70, 190.)

The federal government's compelling interest in issues relating to informed consent is apparent based on the detailed requirements set forth in the regulations for a researcher to follow in obtaining informed consent. In addition to the requirements noted above, 21 C.F.R. § 50.25 provides in relevant part:

> (a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:
>
> (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
>
> (2) a description of any reasonably foreseeable risks or discomforts to the subject.
>
> (3) a description of any benefits to the subject or to others which may reasonably be expected from the research.
>
> (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
>
> (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained…
>
> (6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatment are available if injury occurs…
>
> (7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights…
>
> (8) a statement that participation is voluntary…

Further, 21 C.F.R. § 50.27 mandates that "informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent." The consent form must either embody

the elements of informed consent set forth in § 50.25 or a short form may be used which states that those elements have been presented orally. 21 C.F.R. § 50.27.

Furthermore, in addition to providing specific guidelines as to information that must be contained in a consent form used in a clinical trial, the FDA exercises oversight of clinical trials through an inspection and enforcement regime to ensure that regulatory violations which occur are corrected, including those pertaining to informed consent. When deficiencies are found, the FDA may issue a warning letter. For example, warning letters are issued by the FDA against the sponsor of a clinical trial for failure to protect a subject's legal rights pursuant to 21 C.F.R. § 50.20, for including exculpatory language in a release in contravention of the federal requirement and for failing to obtain proper informed consent by failing to include all of the "eight basic elements" required for an informed consent document pursuant to 21 C.F.R. § 50.25. See, e.g., January 19, 2007 FDA warning letter to Avlon Industries, attached hereto as Exhibit "C" (available to the public on the FDA website). Furthermore, pursuant to 21 C.F.R. § 812.119, the FDA has the authority to disqualify a clinical investigator for repeated violations of FDA regulations, including failure to obtain proper informed consent based on the regulatory requirements. See, e.g., August 24, 2005 Notice of Initiation of Disqualification Proceedings and Opportunity to Explain to Jeffrey L. McLeod, M.D., attached hereto as Exhibit "D" (available to the public on the FDA website).

The FDA regulations and enforcement mechanism described above demonstrate the federal government's compelling interest in clinical trials and in particular as relates to issues relating to informed consent. The government regulations are clearly controlling and the Court will have to interpret them to resolve the issue of whether defendants obtained proper informed

consent from Mr. Mack. As such, there is a substantial federal question which requires that this action should be resolved in a federal forum.

**2. Plaintiff may not avoid removal jurisdiction by avoiding reference in the Complaint to federal regulations governing informed consent in clinical trials**

Plaintiff relies on the "well-pleaded Complaint rule" for the proposition that "the party who brings suit is master to decide what law he will rely on." (See The Fair v. Kohler Dye and Specialty Co., 228 U.S. 22 (1913)). At the same time, however, "it is an independent corollary to the well-pleaded Complaint rule that a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint." Franchise Tax Bd. v. Construction Laborers Vacation Trust, 463 U.S. 1, 22 (1983). Under the "artful pleading" doctrine, a plaintiff may not "avoid removal jurisdiction by artfully casting ... essentially federal law claims as state-law claims." McClure Telephone Co., supra, at 705. The "artful pleading doctrine" allows federal courts to exercise jurisdiction, even when a federal claim does not appear on the face of the plaintiff's complaint, if (1) federal law has completely preempted the state law that serves as the basis for plaintiff's complaint, or (2) a federal question, not pleaded in the plaintiff's complaint, is nonetheless both intrinsic and central to the plaintiff's cause of action. Guckin, et.al. v. Deborah Nagle, et.al., 259 F.Supp. 2d. 406, 410 (E.D. Pa. 2003)(citations omitted)[8].

In the Complaint filed in this action, the artful pleading doctrine is clearly applicable in light of plaintiff's omission of reference to federal regulations governing informed consent in clinical trials – which regulations plaintiff herself cited and relied upon in a prior action

[8] Guckin is factually similar to the instant matter in that plaintiff alleged injury in the course of her participation in a clinical trial of an investigational medical device. The District Court ultimately granted plaintiff's motion to remand the case to state court, finding, *inter alia*, that no substantial federal question was presented. Guckin, however, is readily distinguishable from the instant matter in that it was decided before the Supreme Court's decision in Grable, and followed certain pre-Grable case law, in concluding that the availability of a federal remedy for violating a federal statute was a prerequisite for the exercise of federal question jurisdiction. As discussed infra, this conclusion was specifically disavowed by the Supreme Court of the United States in its Grable opinion.

involving the same claims and substantially similar averments. See Exhibit "B". Plaintiff's dismissal of the prior action in which she relied upon the federal regulations for relief belies her contentions that the conduct herein is actionable under the Pennsylvania MCARE Act, which on its face has no applicability to the alleged factual basis for claims asserted herein. The FDA (and HHS) regulations necessarily invoke substantial federal questions pertaining to informed consent and experimentation regarding human subjects. See 21 C.F.R. §50.20; 45 C.F.R. §46.116. The meaning and interpretation of these regulations are essential to a resolution of plaintiff's state law claims for battery and fraudulent misrepresentation.

The Supreme Court's decision in Grable, supra, is instructive as to the type of state law claim which presents a substantial issue of federal law permitting the exercise of federal question jurisdiction. The petitioner in Grable was a company which owned property in Michigan that was seized by the IRS as a result of a tax delinquency. The IRS subsequently sold the property to a second company in a tax sale. The petitioner brought a quiet-title action in Michigan state court against the company which purchased the property from the IRS. Petitioner Grable alleged that the sale was invalid because the IRS had not given adequate notice within the meaning of a federal statute requiring notice. Grable, 545 U.S. at 311. Respondent Darue removed the case to federal court on the basis that it presented a federal question because the claim of title depended on the interpretation of the federal tax statute regarding notice. The District Court denied petitioner Grable's motion to remand the case, finding that the claim posed a significant question of federal law and that Grable's lack of a federal right of action did not bar the exercise of federal jurisdiction. The Court of Appeals for the Sixth Circuit affirmed.

The Supreme Court granted certiorari on the jurisdictional question alone and affirmed the Sixth Court's decision. Acknowledging that federal-question jurisdiction is typically invoked by plaintiff's pleading a cause of action under federal law, the Court stated:

> There is, however, another longstanding, if less frequently encountered, variety of federal "arising under" jurisdiction, this court having recognized for nearly 100 years that in certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues. The doctrine captures the common sense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justified resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.

Id., 545 U.S. at 312 (citations omitted). The Court determined that whether Petitioner was given notice within the meaning of the Federal statute was an essential element of its quiet-title claim. "The meaning of the federal tax provision is an important issue of federal law that sensibly belongs in a federal court." Id. at 318.

Similarly, in the instant matter, whether defendants appropriately obtained Mr. Mack's consent within the meaning of the federal regulations governing informed consent is an essential element of plaintiff's battery and fraudulent misrepresentation claims. Plaintiff contends that HUP and the physician-defendants failed to obtain Mr. Mack's informed consent to participate in the FDA regulated VentrAssist Study. Specifically, plaintiff alleges that:

> William Mack was not advised by his University of Pennsylvania healthcare providers of any limitation on his legal rights in the event that he was implanted with a defective VentrAssist LVA4, or that either the University of Pennsylvania and/or Ventracor believed, at the time he executed the Consent Form, **that he had no substantive legal rights in relation to his recruitment into and participation in the VentrAssist Study**, or arising out of the implantation of a defective VentrAssist LVA4 into his body.

See Exhibit "A" at ¶ 179 (emphasis added). In particular, plaintiff has challenged the language of the consent form signed by Mr. Mack based on the assertion that it misrepresented to Mr. Mack his legal rights.

The Grable Court noted that in determining whether a federal question is a substantial one, courts should inquire into whether resolution of the issue in federal court would benefit from "the advantages thought to be inherent in a federal forum." Id., 545 U.S. at 313. Just as the Grable Court recognized the strong federal interest in tax litigation, this Court should recognize the strong federal interest in the regulation of clinical trials involving human subjects and particularly the need for uniform application of FDA and HHS regulations pertaining to informed consent. Rather than tipping the balance of division of labor between federal and state courts, federal jurisdiction in this matter is necessary to maintain uniform standards regarding informed consent. This case arises in the broader context of an FDA-approved clinical trial involving a medical device. It is readily apparent that there is a strong federal interest in ensuring for the consent of research subjects in medical experimentation and a consistent interpretation of federal regulations governing informed consent.

Other Courts addressing the scope of the Grable decision have focused on whether the "federal question" presented is one that is essentially a pure question of law as opposed to being fact and situation specific. See Pennsylvania Employees Benefit Trust Fund (the "Fund") v. Eli Lilly & Company, Inc., et.al., 2007 WL 2916195 (E.D. Pa. October 5, 2007). In that case, the Fund filed a lawsuit in state court against defendant pharmaceutical companies alleging, among other things, that the companies promoted and marketed their respective drugs for non-medically necessary uses and caused the Fund's participants to improperly submit claims for reimbursement by the Fund. Defendants argued that the FDA's exclusive control over labeling

of medicines required a federal forum for the resolution of plaintiff's claims. The Court granted plaintiff's motion to remand finding that the central dispute in this case involved a factual issue, i.e., whether the defendants' advertising and promotion methods violated Pennsylvania tort law, as opposed to interpretation of federal law. Id. at *5-6.

The difference between this case and Pennsylvania Employees Benefit Trust Fund, supra, is that the issues presented to this Court are not "fact-bound" and "situation-specific", as was the case in Pennsylvania Employees Benefit Trust Fund. Id. at *4. Rather, as in Grable, supra, this case involves a pure issue of law – the required information that must be presented to a clinical research subject in the context of obtaining informed consent as to legal rights (and non-waiver thereof) pursuant to an FDA-approved clinical trial. Further, as in Grable, and in contrast to Pennsylvania Employees Benefit Trust Fund, the claims asserted by plaintiff turn on disputed issued of federal law, in this case specific FDA regulations addressing informed consent. The Court's resolution of these issues will help to guide informed consent for all research patients participating in clinical trials. Accordingly, this Court may and should exercise jurisdiction over this litigation, in order to address this substantial federal question.

### C. A Federal Private Cause of Action is Not a Condition for the Exercise of Federal Question Jurisdiction

Plaintiff asserts that since none of the federal regulations cited by defendants allow for a federal private right of action or remedy, there is no basis for the exercise of federal question jurisdiction for plaintiff's state tort claim of battery. In Grable, supra, however, the Supreme Court, commenting on its earlier decision in Merrell Dow Pharmaceuticals Inc. v. Thompson, 478 U.S. 804 (1986), specifically rejected this viewpoint, finding that a federal cause of action is not a requirement for exercising federal question jurisdiction:

> Accordingly, *Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant

> to, but not dispositive of, the "sensitive judgments about congressional intent" that §1331 requires.

Id., 545 U.S. at 318.

Plaintiff relies on Gonzaga Univ. v. Doe, 536 U.S. 273 (2002) and Cort v. Ash, 422 U.S. 66 (1975) to support her argument that federal court jurisdiction is not appropriate where the federal law, here the federal regulations noted above, do not provide for a federal right of action or an inferred right of action. From the outset, it is noteworthy that neither Gonzaga nor Cort addressed the issue of whether the federal court had subject matter jurisdiction on the basis of a federal question being presented. Both cases arise from completely different procedural postures than from the instant matter. Both cases were decided prior to the Supreme Court's Grable decision; both involved plaintiff attempting to assert a private claim under a federal statute where no private claim was provided; and, both involved administrative schemes to address the circumstances from which plaintiffs asserted that their actions arose.[9]

Defendants do not argue that a federal private right of action was created as a corollary to the regulations involving informed consent in this matter. There is, however, a basis to conclude from the text and structure of the regulations themselves that Congress intended these regulations to be construed, if necessary, in a federal court setting. See Alexander v. Sandoval, 532 U.S. 275 (2001). The regulations fall under the category of "Protection of Human Subjects" and are phrased in terms of the persons benefitted- those persons who become subjects of human experimentation. The meaning and interpretation of these regulations in the context of the FDA's protocol for use of an investigational medical device requires that a federal forum address plaintiff's battery claim.

[9] Notably, plaintiff's memorandum in support of her request for remand neither cites not discusses the controlling Grable opinion.

## IV. PLAINTIFF IS NOT ENTITLED TO FEES OR COSTS WERE THIS COURT TO DECLINE TO EXERCISE JURISDICTION OVER THIS MATTER

Plaintiff has moved for an award of costs and attorney's fees incurred as a result of the removal pursuant to 28 U.S.C. § 1447(c). The Supreme Court has held that "[a]bsent unusual circumstances, courts may award attorney's fees under § 1447(c) only where the removing party lacked an objectively reasonable basis for seeking removal. Conversely, when an objectively reasonable basis exists, fees should be denied." Martin v. Franklin Capital Corp., 546 U.S. 132, 141 (2005). If removal is patently "frivolous" or "insubstantial," then granting attorney fees is appropriate. Mints v. Educ. Testing Serv., 99 F.3d 1253, 1261 (3d Cir. 1996). It is axiomatic that "removal is not objectively unreasonable solely because the removing party's arguments lack merit." Lussier v. Dollar Tree Stores, Inc., 518 F.3d 1062, 1065 (9th Cir. 2008).

In this case, regardless of the Court's ultimate determination of the issue of whether there is a substantial question of federal law that gives rise to federal court jurisdiction, it cannot reasonably be contended that responding defendants have acted in a fashion that would justify an award of sanctions pursuant to 28 U.S.C. § 1447(c). The legal arguments set forth above in support of responding defendants' opposition to plaintiff's motion for remand clearly establish that responding defendants acted in an objectively reasonable basis in removing the case to federal court. See First American Marketing Corp. v. United Integrity Group, 2009 U.S. Dist. LEXIS 63721 (E.D. Pa. July 22, 2009) (Stengel, J.) (Court declined to award attorneys fees and costs where defendants' contentions in support of federal court jurisdiction were not "manifestly frivolous"); U.S. Healthcare, Inc. v. Reliastar Fin. Corp., 1996 U.S. Dist. LEXIS 18963, *3 (E.D. Pa. December 16, 1996) (Hutton, J.) (An award of fees and costs pursuant to § 1447 should be granted "only where the removal of the case was made in bad faith and was clearly without legal support."); Kostmayer Construction, LLC v. MR Pittman Group, LLC, 2007 U.S. Dist. LEXIS

97177 (E.D. La. December 19, 2007)(Court denied request for attorney's fees and costs based on determination that defendant had not acted in bad faith in seeking removal and removability of the suit did not rest on application of a bright line rule).

Accordingly, even if the Court declines to accept jurisdiction and orders that the case be remanded to state court, plaintiff's request for attorney's fees and costs should nevertheless be denied.

## V. CONCLUSION

For the reasons set forth in this Memorandum of Law, responding defendants respectfully request that this Honorable Court deny plaintiff's Motion to Remand this case to the Philadelphia County Court of Common Pleas. A form of Order is submitted for the Court's consideration.

Respectfully submitted,

BY: _____

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Dated: 7/7/10

**CERTIFICATE OF SERVICE**

Richard S. Margulies, Esquire, hereby certifies that on this date he caused Defendants' Response In Opposition To Plaintiff's Motion To Remand and For Costs, Expenses and Attorneys' Fees and Memorandum of Law In Support, to be served by electronic means and U.S. First-Class Mail upon counsel listed below:

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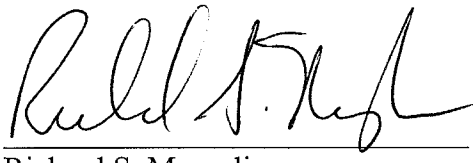

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